K121113
1/2

Biopsy Sciences

JUL 12 2012

510(K) SUMMARY (21 CFR 807.92)

HYDROMARK BIOPSY SITE MARKER

510(k) Owner: Biopsy Sciences, Inc.
4900 Creekside Drive, Suite C
Clearwater, FL 33760
Tel: 727-290-9825
Fax: 727-290-9828

Contact Person: Sharon Rockwell
Tel: 714-695-9269
E-mail: srockwell@writeme.com

Date Prepared: July, 2012

Trade Name: HydroMark Biopsy Site Marker

Common Name: Biopsy site marker

Classification Name: Implantable clip per 21 CFR 878.4300, NEU

Predicate Devices: Biopsy Sciences HydroMark Breast Biopsy Site Marker, K060769
Biopsy Sciences HydroMark Breast Biopsy Site Marker, K083006
Biopsy Sciences HydroMark Breast Biopsy Site Marker, K090501

Device Description: The HydroMark Breast Biopsy Site Marker contains a resorbable hydrogel component and a metallic component for permanent marking. The hydrogel has features that are unique and highly desirable for breast tissue marking.

The HydroMark Site Marker is provided pre-loaded in a sterile, disposable applicator that is compatible with specified commercially available biopsy devices. The HydroMark is deployed by the delivery system and is left in the tract created during the biopsy procedure.

The Biopsy Sciences HydroMark Breast Biopsy Site Markers will have a change in vendor for the supplier of the hydrogel material. The change in the supplier of the hydrogel has no effect on the finished product specifications.

K121113
2/2

Intended Use:	To mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.
Technological Characteristics:	The hydrogel component expands on fluid contact to fill the track of the biopsy needle anchoring the HydroMark at the exact location of biopsy. Because the hydrogel is hydrophilic, it is clearly distinct from normal breast structure under ultrasound imaging. The hydrogel material degrades via hydrolysis over time leaving the internal stainless steel or titanium coil which provides permanent visibility under x-ray and MRI.
Non-Clinical Performance Data:	Non-clinical testing included physical, functional and biocompatibility of the finished products manufactured in a newly qualified facility, using hydrogel material from a new supplier. The devices performed as intended according to the original specifications established for the finished device.
Conclusions:	The testing supports a determination of substantial equivalence to predicate devices cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biopsy Sciences, LLC
% Ms. Sharon Rockwell
Consultant
5582 Chalon Road
Yorba Linda, Florida 33760

JUL 12 2012

Re: K121113
Trade/Device Name: Biopsy Sciences HydroMark Breast Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: April 09, 2012
Received: April 12, 2012

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

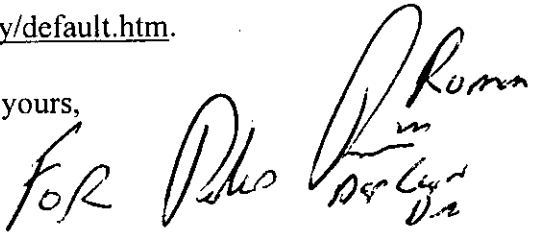
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121113

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Biopsy Sciences HydroMark Breast Biopsy Site Marker

Indications for Use:

To mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121113